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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,582	12/05/2003	Kenji Mori	MUR-037-USA-P	7344

7590 09/14/2004

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/727,582	Applicant(s) MORI ET AL.	
	Examiner Mark W Bockelman	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03-19-2004</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is an apparatus claim which positively recites a mucous membrane by reciting that the extraction pad is applied to the mucous membrane. 35 U.S.C. 101 prohibits applicant from claiming a part of a human body as part of their invention. Applicant may recite the body as an intended use, for example, by reciting an extraction pad *adapted to be placed in contact with a mucous membrane* instead.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollinsworth USPN 569380 or Higo et al USPN 6,006,130.

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Hollinsworth shows two electrode members (a ), extraction pads (b) fixing members C , F' that are situated to intersect (cross) at pin f' in a rotatable manner with spring member H affixed thereto. Higo et al shows a similar arrangement with spring 37 and various electrode pad structures seen in figures 11(a) and 11(b). Applicant's statements of intended use provide no structural distinction since both references are capable of performing the functions recited.

Claims 1, 3-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tapper USPN 6,059,736. Tapper teaches and iontophoresis system that may extract analytes including glucose (as well as aspirin levels –see applicant's claim 4) using a sensor and an extraction period designed to complete extraction within ten minutes (see column 2 lines 22-28, as well as claim 7 of Tapper). A plurality of electrodes are provided in the system including drug delivery electrodes 16 a and b, return ground electrodes 63, 64 and sample analyzing electrodes 67, 68. An extraction pad 74 receives extracted body fluids for analysis. An ExacTech<sup>R</sup> meter provides a readout for the level of glucose and time varying circuitry for controlling the sampling period (see claim 1 'means for varying time") are provided. With respect to claim 4, Tapper teaches that aspirin concentration can be measured, a substance capable of being delivered as well.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapper USPN 6,059,736 in view of Cormier et al. USPN 6,219,574. Applicant differs in reciting that the extraction pad is an ion exchange resin and that the method (claim 9) includes sampling the mucosa membrane of a patient. Cormier et al teaches a sampling device that may be applied to skin or mucosa (column 7 lines 40-47) for sampling. The pad used in sampling may be an ion exchange material to aid in retaining the analyte (column 3 lines 32-42). To have provided the Tapper device with a similar membrane and to have selected the mucosa as the sampling surface would have been obvious since such was well known at the time of applicant's invention as evidenced by Cormier et al..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

September 11, 2004

  
MARK BOCKELMAN  
PRIMARY EXAMINER